# Opioid Prescribing, Addiction and Opioid Abuse in the US and Indiana

Dmitry Arbuck, MD

Clinical Assistant Professor of Psychiatry and Medicine, IU School of Medicine

President and Medical Director,

Indiana Polyclinic

## Disclosure

No conflicts of interests

# Questions

- Who is (are) responsible for the opioid epidemic in the US?
- What demographic categories are at the highest risk of opioid use disorder?
- What are the ways to diminish opioid associated morbidity and mortality?

# Introduction

Pain is a universal health problem that people have had to deal with since the birth of civilization. In the pursuit of pain control, opioids have become the default for pain management. By the early 2000s, excessive opioid use came to be associated with an increase in both morbidity and mortality and on October 26, 2017, President Trump declared the opioid crisis a national Public Health Emergency. Education about the opioid epidemic became a regulatory matter and many States, including Indiana, started to mandate opioid education as a prerequisite to prescribing controlled substances.

# Death

# Opioid Task Force 2020 Progress Report released by the American Medical Association (AMA) August, 2020

- Development away from prescription opioids

- Dramatic increase in overdose fatalities involving illicit opioids, but a simultaneous dramatic drop in the use of prescription opioids
- Opioid prescribing decreased for a sixth year in a row (a drop of 37.1 percent, or more than 90 million opioid prescriptions between 2014 and 2019)

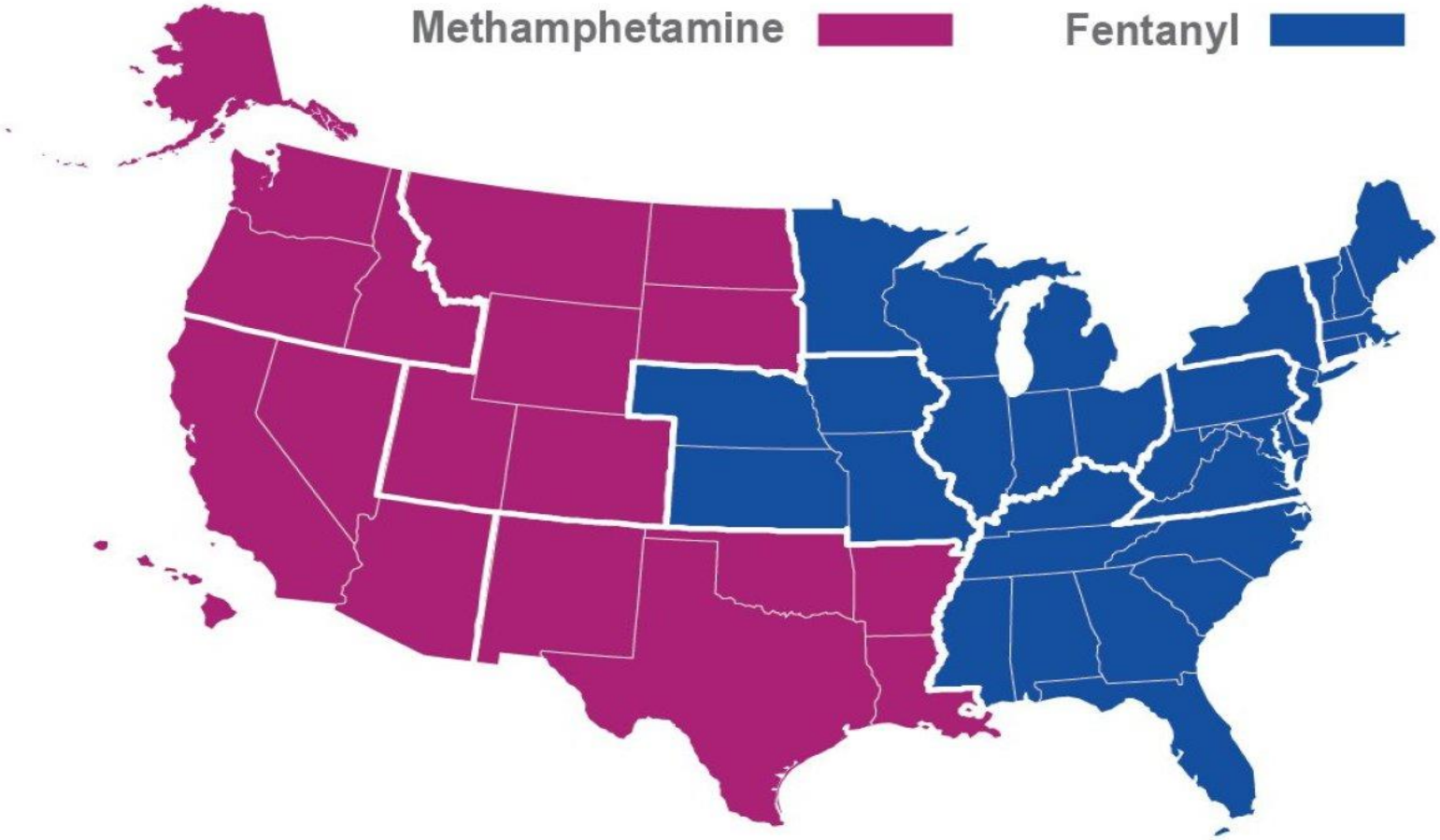
# Opioid Overdoses Rising 2005 -2018

- The percentage of patients admitted to a critical care unit increased from 6.6% to 9.6%.
- Deaths increased from 0.18% to 0.28%.
- The likelihood of the overdose being life-threatening and resulting in significant disability or disfigurement increased from 0.10% to 0.13%.
- Suicidal intent increased from 13.9% to 22.2%.
- Naloxone administration increased from 42.3% to 50.8%.
- 70% of people who use opioids for nonmedical reasons get them from family and friends.

- Society of Critical Care Medicine's 49th Critical Care Congress (Crit Care Med 2020. doi: 10.1097/01.ccm.0000618708.38414.ea)

# Drug overdose deaths by region

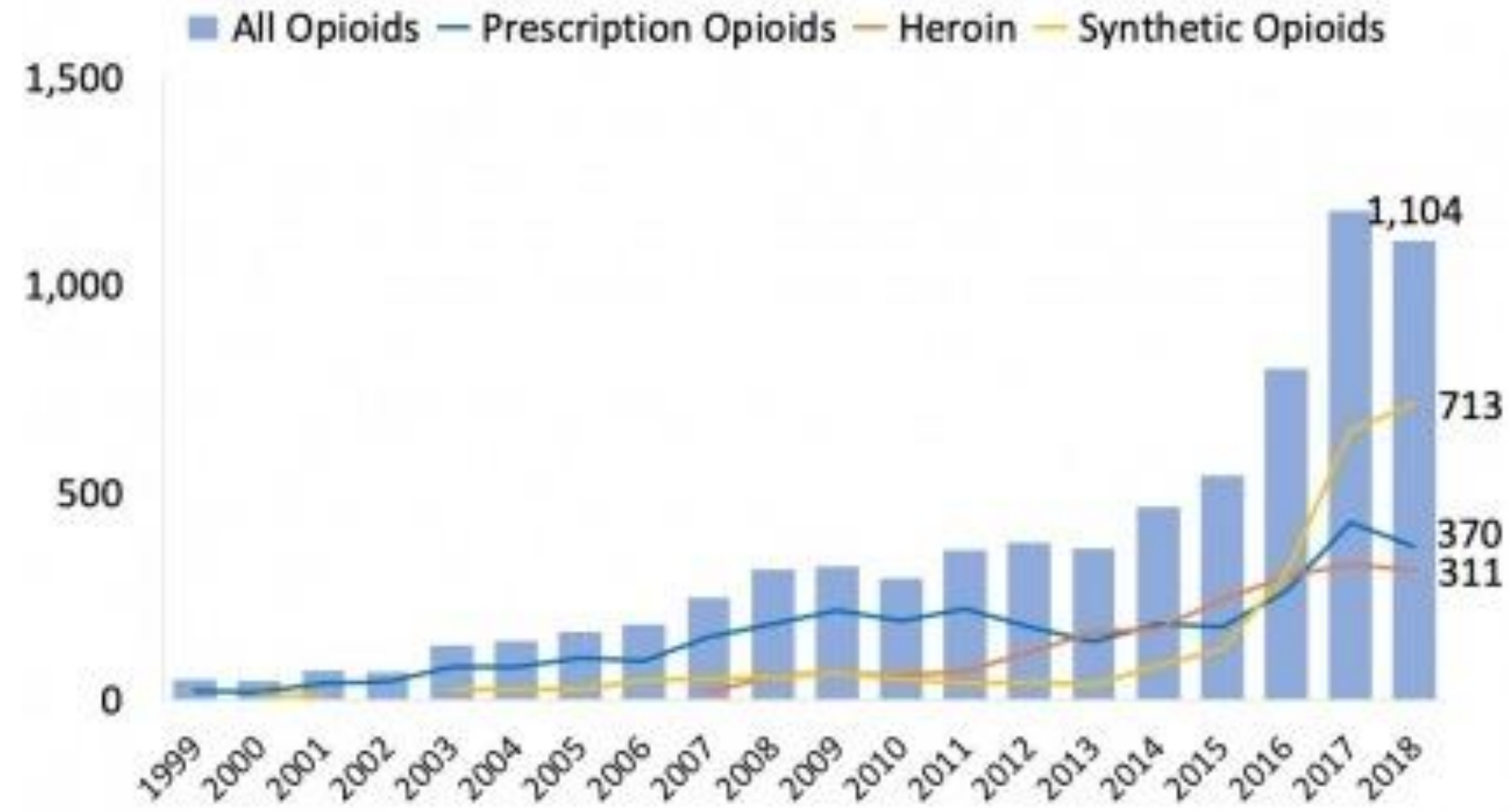
Methamphetamine was the top drug involved in overdose deaths in most of the western half of the U.S. while fentanyl pervaded the eastern half.




NOTE: Data from 2017. Deaths may include additional drugs.
SOURCE: NCHS National Vital Statistics System

AP

# Drug overdose deaths involving opioids in Indiana, by opioid category




https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/indiana-opioid-involved-deaths-related-harms

# More Than Two-Thirds of Overdose Deaths in 2017 Involved Opioids, US

67.8 percent of the 70,237 drug overdose deaths in 2017 involved an opioid

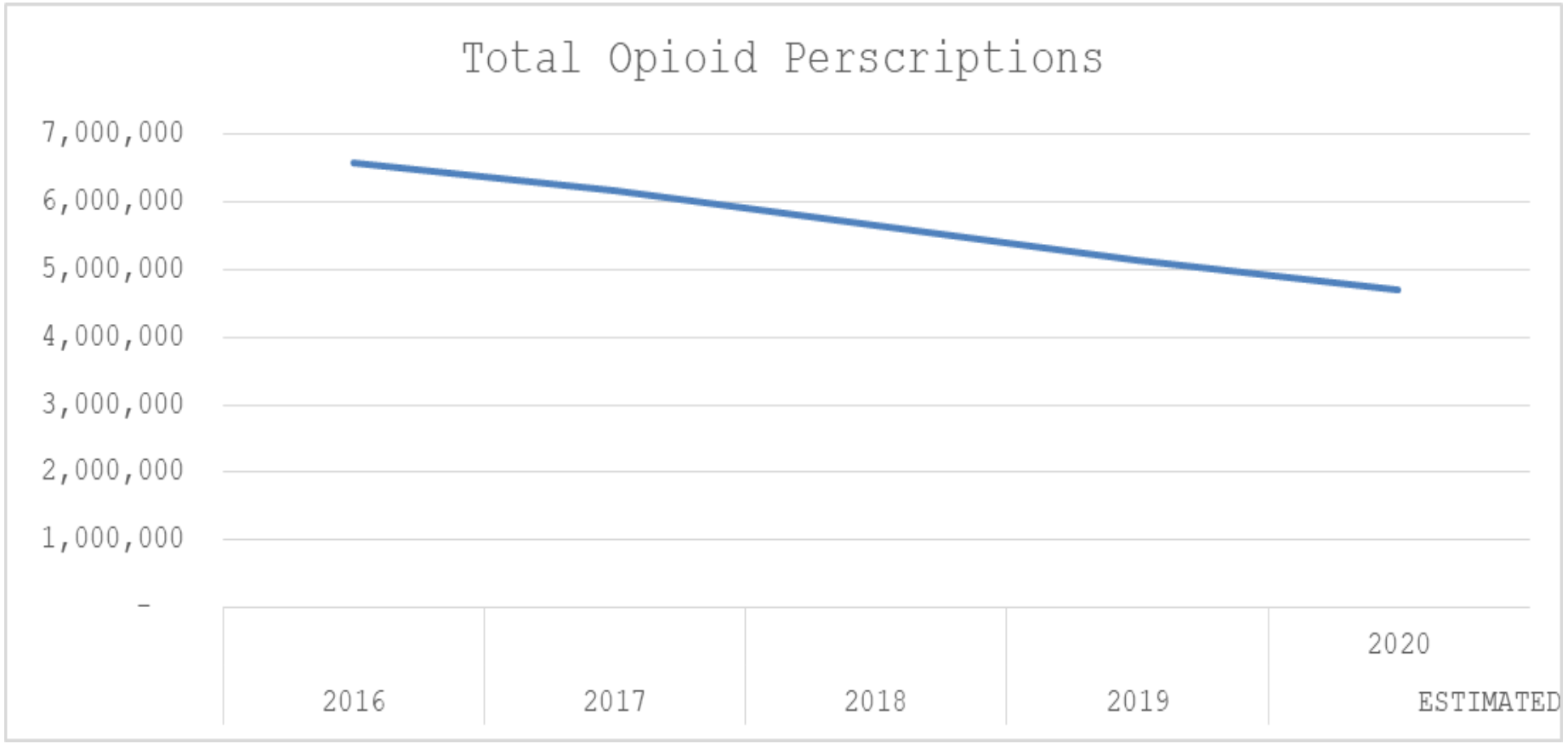
CDC Weekly Report. Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017 Weekly / January 4, 2019 / 67(5152);1419–1427 accessed at https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm

# Opioid prescriptions and Overdoses in 2018 in Indiana

- 65.8 opioid prescriptions for every 100 persons compared to the average U.S. rate of 51.4 prescriptions (1)
- Opioids were involved in 46,802 (a rate of 14.6) overdose deaths in 2018— nearly 70% of all overdose deaths (2)


1. Centers for Disease Control and Prevention. U.S. Opioid Prescribing Rate Maps. (2019, October 3). Retrieved from https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html
2. Hedegaard H, Miniño AM, Warner M. Drug overdose deaths in the United States, 1999–2018. NCHS Data Brief, no 356. Hyattsville, MD: National Center for Health Statistics. 2020.

# Opioid prescriptions in Indiana

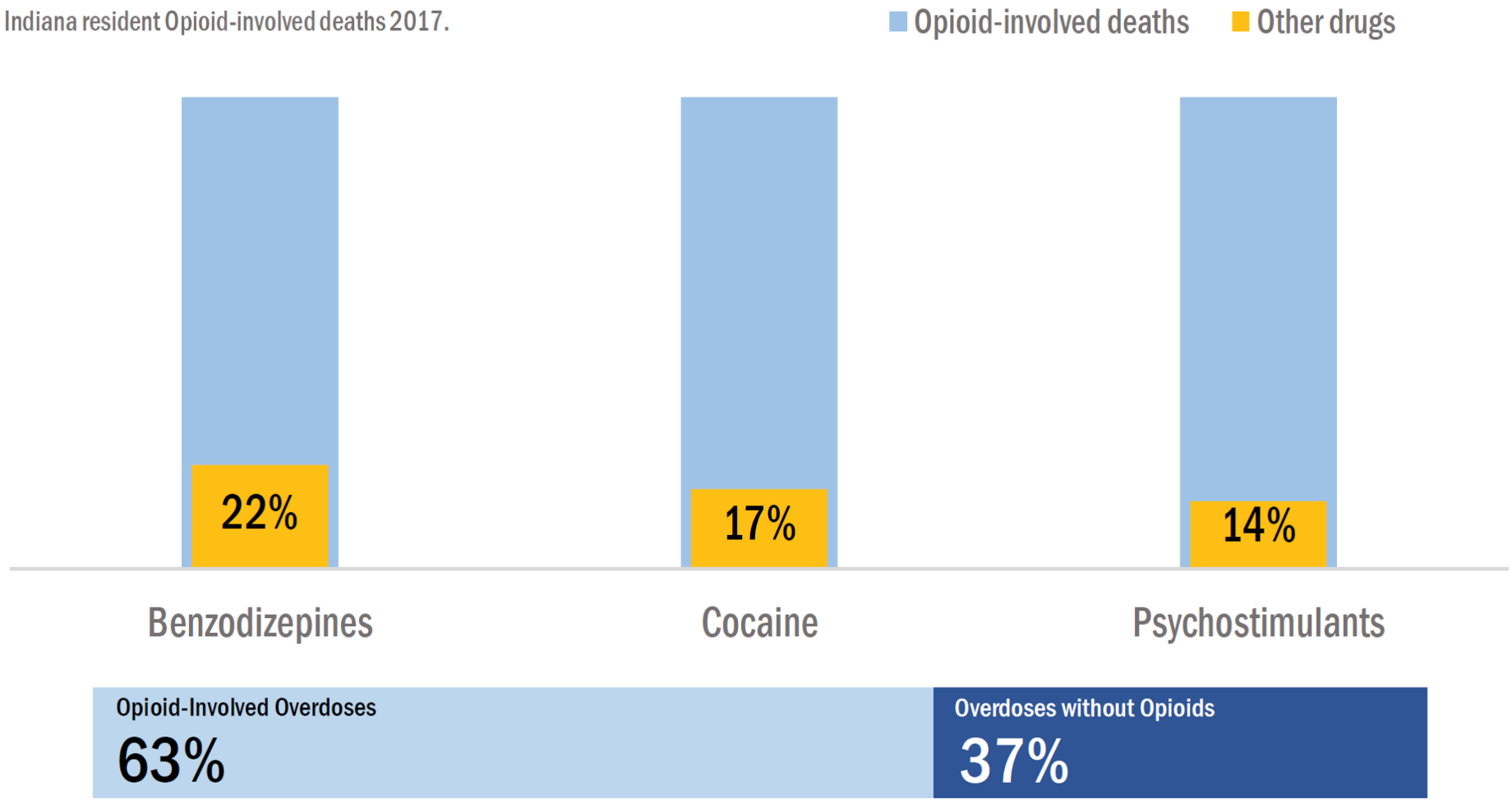



Indiana State Department of Health

# Opioid prescriptions in Indiana

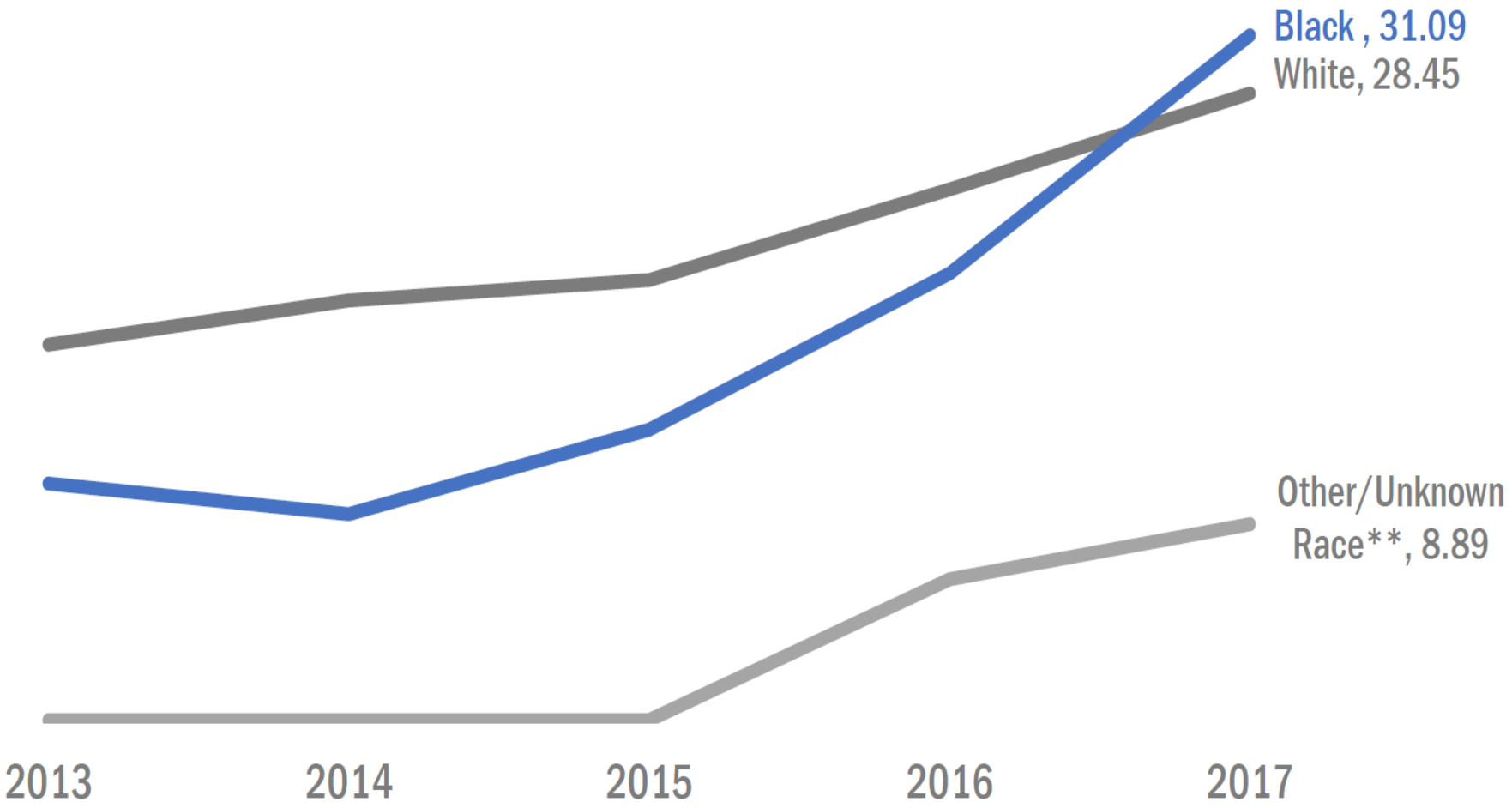
| | 2016 | 2017 | 2018 | 2019 | ESTIMATED 2020 | Actual 2020 (through June) |
|---|---|---|---|---|---|---|
| Total Opioid Perscriptions | 6,589,072 | 6,162,008 | 5,657,665 | 5,146,543 | 4,707,004 | 2,353,502 |
| | | | | | | |
| Gender | | | | | | |
| Male | 57% | 57% | 58% | 58% | | 58% |
| Female | 43% | 43% | 42% | 42% | | 42% |
| | | | | | | |
| 18 & Under | 2% | 2% | 2% | 2% | | 1% |
| 19-29 | 8% | 7% | 7% | 6% | | 6% |
| 30-39 | 14% | 13% | 13% | 12% | | 12% |
| 40-49 | 17% | 16% | 16% | 15% | | 15% |
| 50-59 | 24% | 23% | 22% | 22% | | 21% |
| 60-69 | 19% | 20% | 21% | 22% | | 22% |
| 70-79 | 10% | 11% | 12% | 13% | | 13% |
| 80-89 | 5% | 5% | 6% | 6% | | 6% |
| 90+ | 1% | 2% | 2% | 2% | | 2% |

# Indiana Opioid Associated Deaths



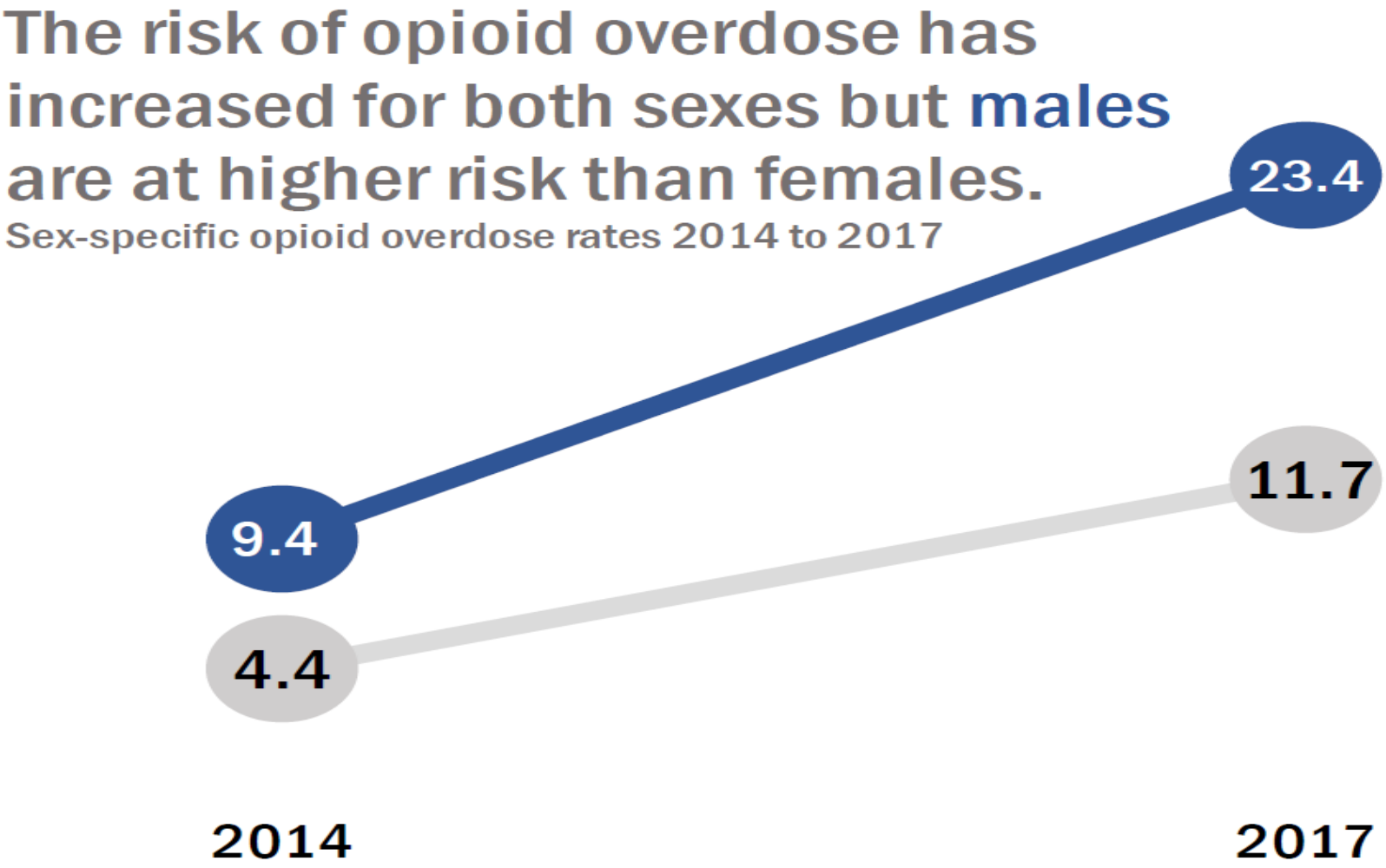

Indiana State Department of Health

# Opioid Death Rate in Indiana

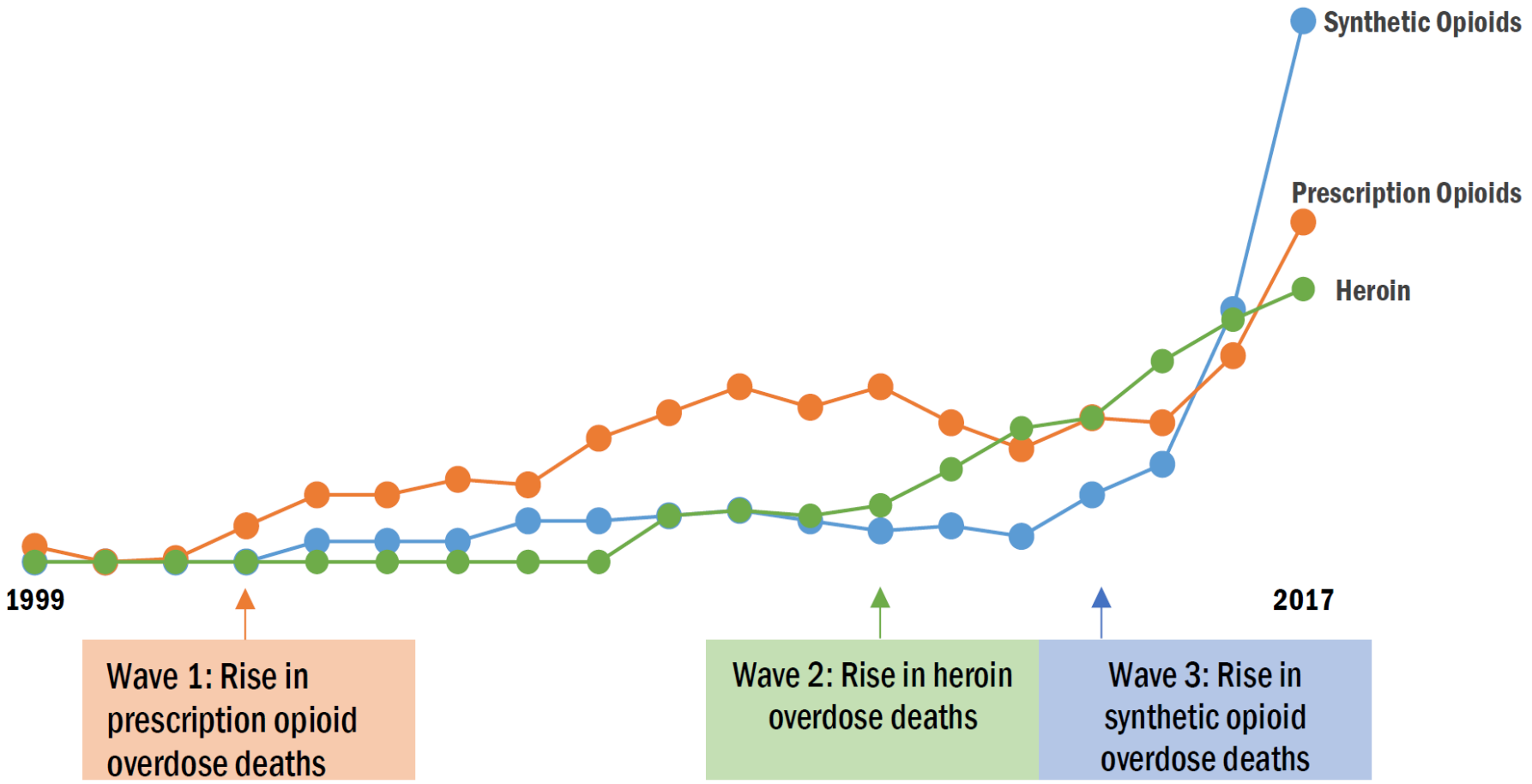



Indiana State Department of Health

# Gender Difference in Opioid Deaths, IN



# Distribution of Opioid Deaths in Indiana

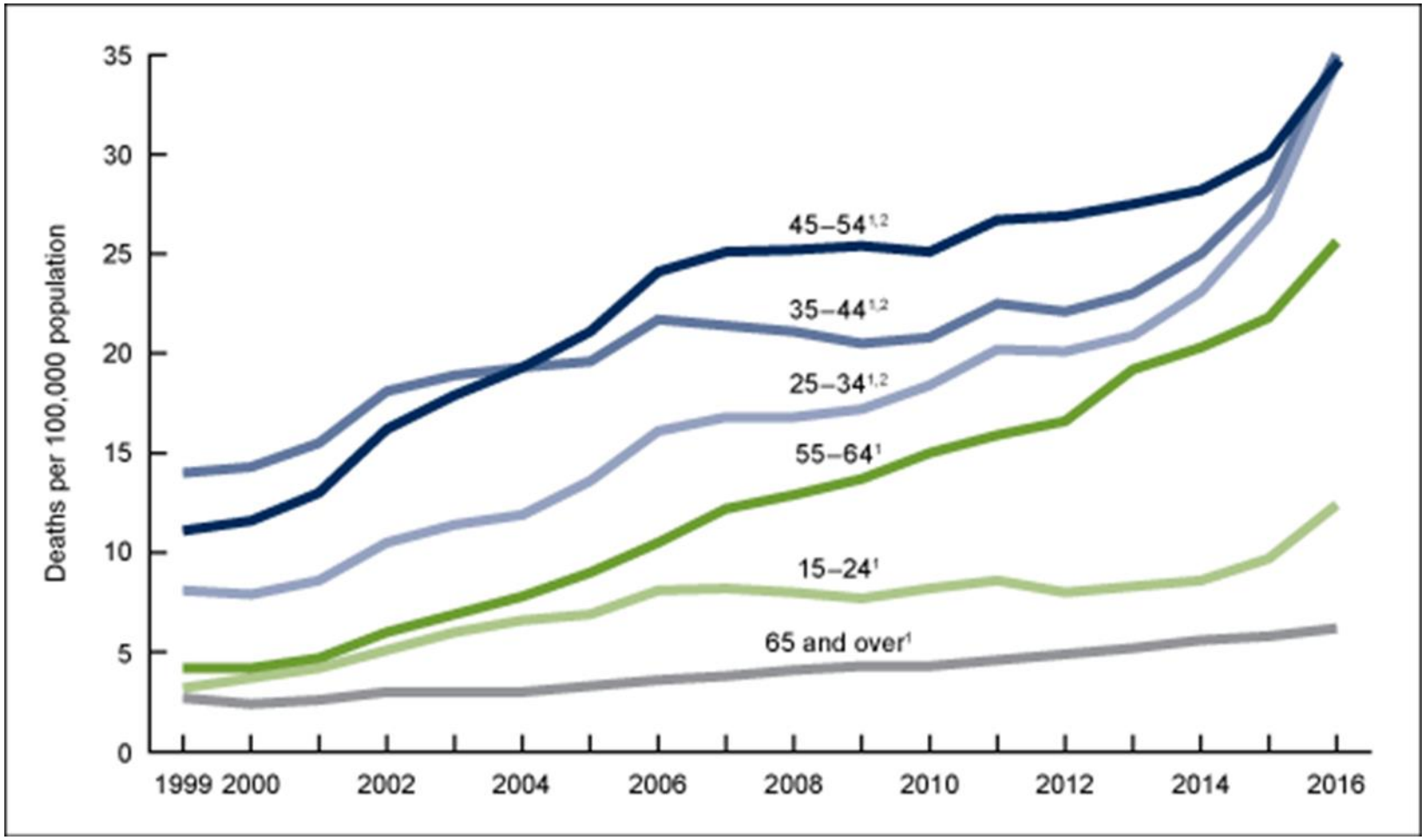


# Drug Overdose in the US

Between 2011 and 2016, the 10 drugs most frequently mentioned in relation to a drug overdose death were: fentanyl (ranked first in 2016), heroin (ranked first from 2012-2015), hydrocodone, methadone, morphine, oxycodone (ranked first in 2011), alprazolam, diazepam, cocaine (consistently ranked second or third), and methamphetamine.

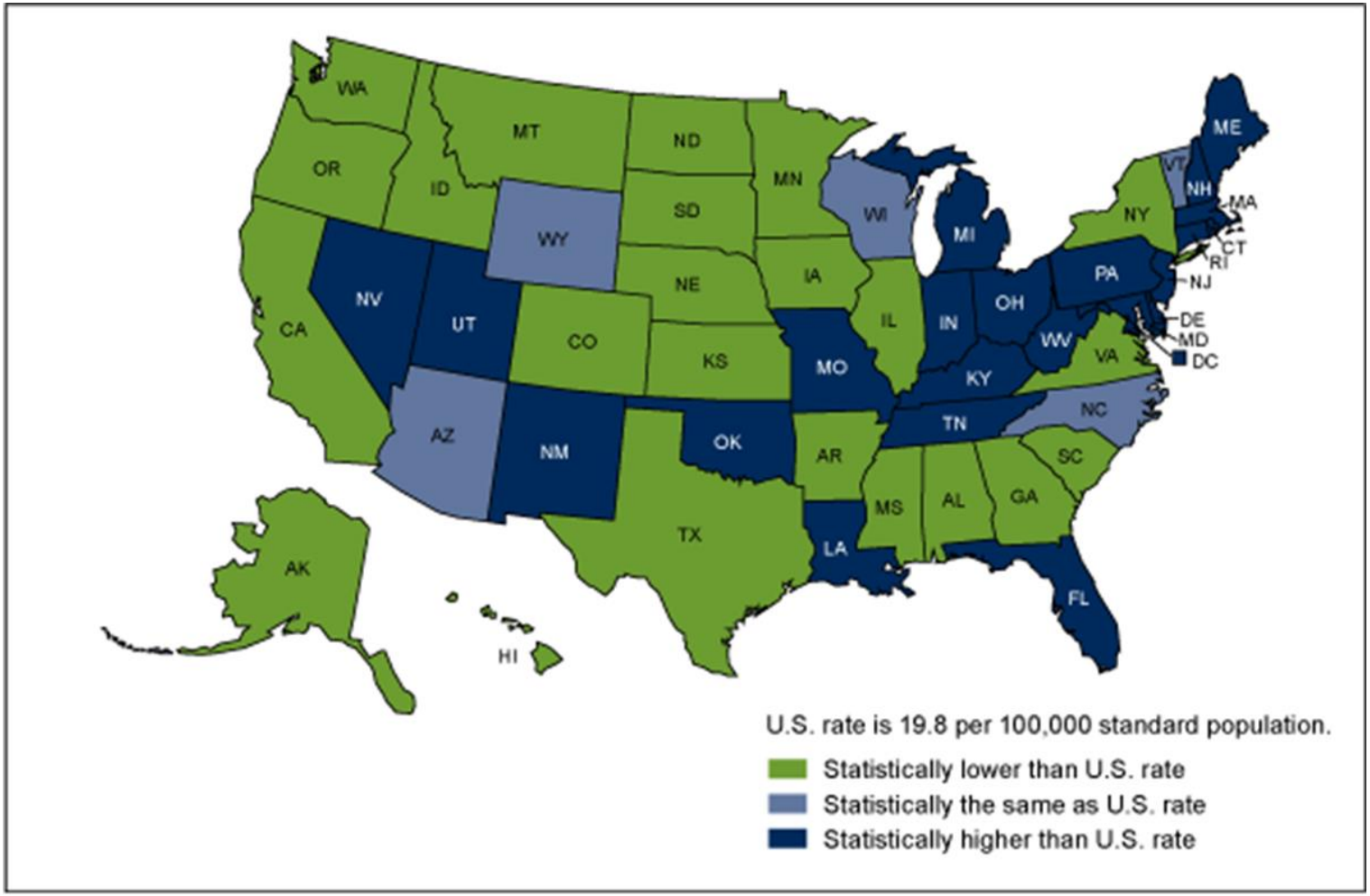
- https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_09-508.pdf

# Drug overdose death rates, by selected age group: United States



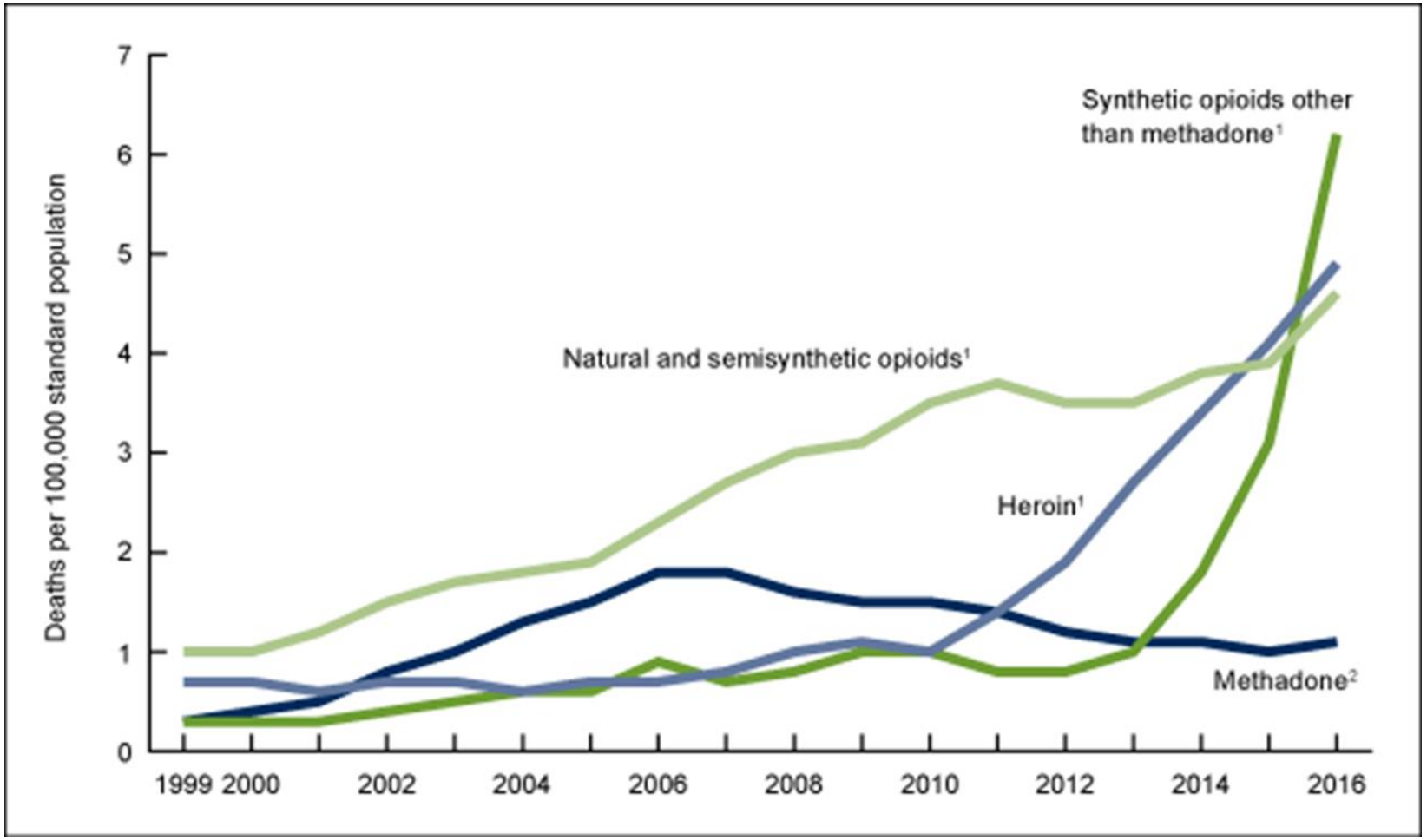

SOURCE: NCHS, National Vital Statistics System, Mortality

# Age-adjusted drug overdose death rates, by state: United States, 2016




SOURCE: NCHS, National Vital Statistics System, Mortality

# Age-adjusted drug overdose death rates, by opioid category: United States

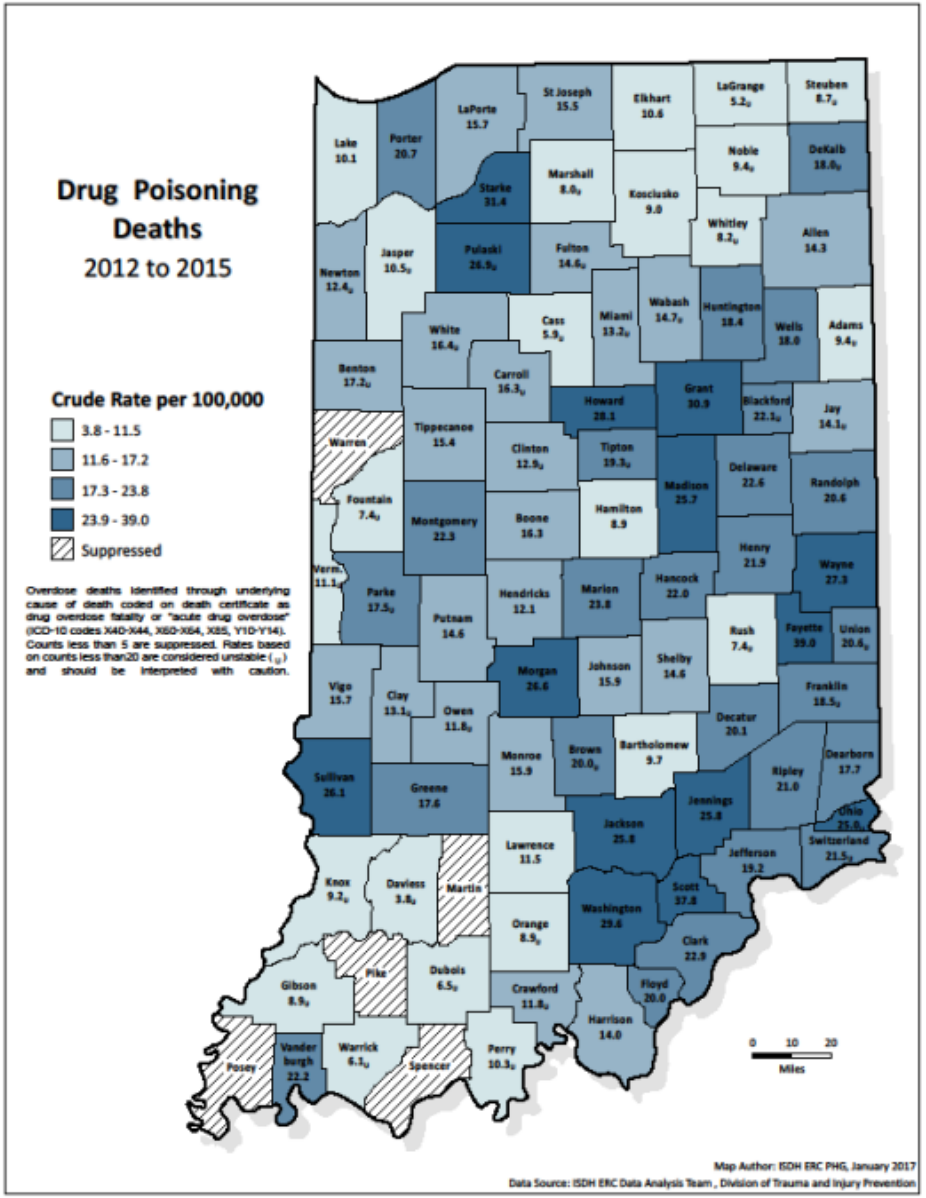


# Opioid-Related Deaths Up Threefold in Children

- 8986 children and adolescents died from prescription and illicit opioid poisonings between 1999 and 2016. Of these, 88.1%, were aged 15 to 19 years, and 6.7% were under 5 years.
- Most deaths were among non-Hispanic whites (79.9%) and males (73.1%).
- Prescription opioids were implicated in 73.0% of deaths

Gaither J, Shabanova V, Leventhal J, US National Trends in Pediatric Deaths From Prescription and Illicit Opioids, 1999-2016 JAMA Netw Open December 28, 2018;1(8):e186558. doi:10.1001/jamanetworkopen.2018.6558

# Indiana Death Certificates (January 2017)




Overdose as cause of death

GREATER THAN 60% of all recent deaths in Indiana are opioid related

# “Holy Trinity”

- Hydrocodone (Norco)
- Carisoprodol (Soma)
- Alprazolam (Xanax)

# Opioid Analgesics and Unemployment

- Patients using opioid analgesics were found to be 3.08 times more likely to be unemployed due to disability than nonusers
- Opioid users were more likely than nonusers to be men vs women (25.0% vs 17.1%)
- Born in the United States vs abroad (64.7% vs 46.8%)
- Native vs non-native English speaking (84.3% vs 76.6%)

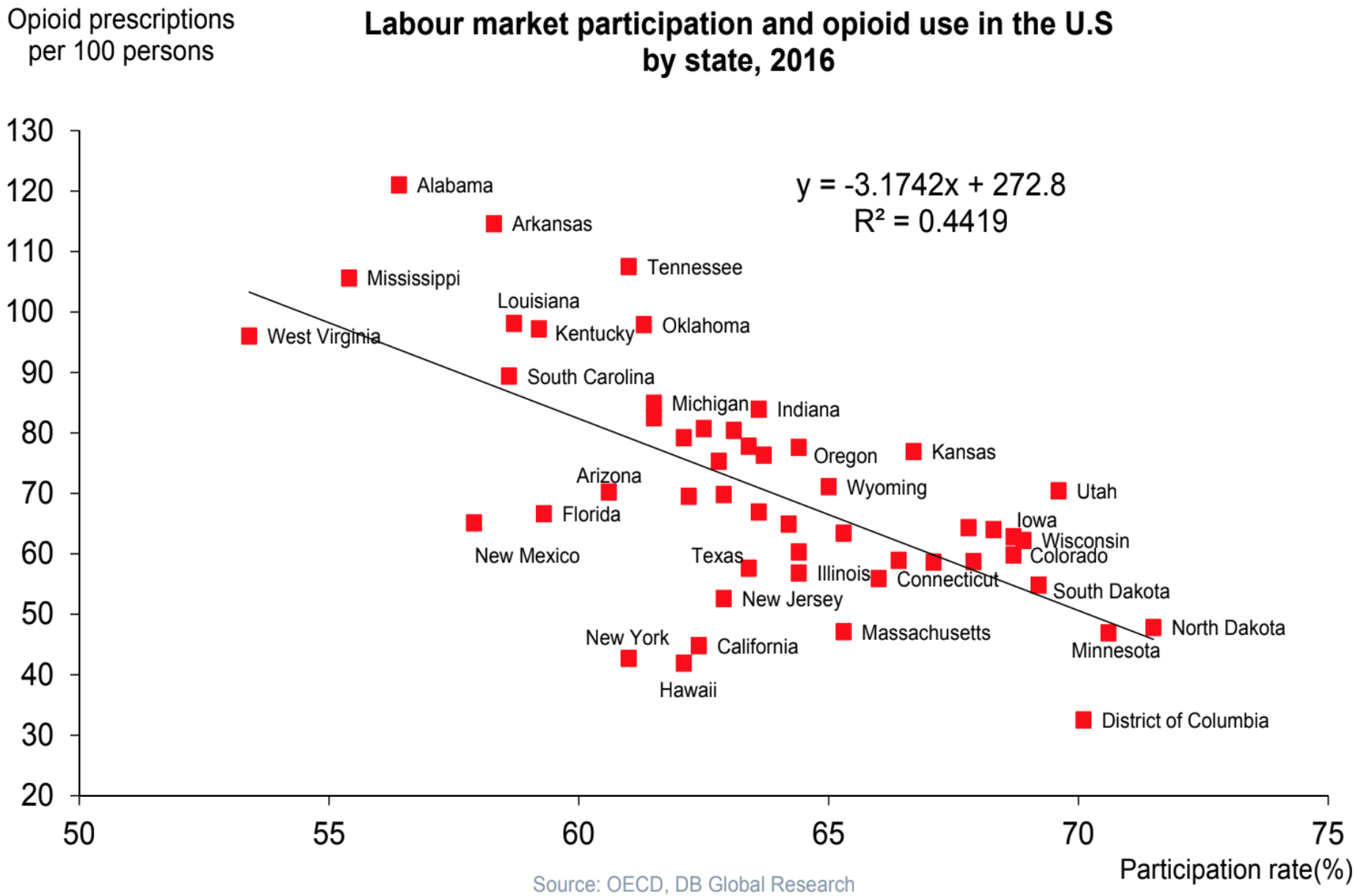
Chuang E, Gil EN, Gao Q, Kligler B, McKee MD. Relationship between opioid analgesic prescription and unemployment in patients seeking acupuncture for chronic pain in urban primary care [published online September 3, 2018]. Pain Med

# Disability

Chronic opioid use negatively correlates with the ability of patients to return to meaningful work.

Volinn E, Fargo JD, Fine PG. Opioid therapy for nonspecific low back pain and the outcome of chronic work loss. Pain. 2009;142(3):194-201.

# Opioid crisis having a negative impact on labor force participation




Source: OECD, DB Global Research

# US production and consumption of opioids

By 2012:

- 53.7% morphine,
- 99% hydrocodone
- 85% oxycodone
- 30%  fentanyl

In the world was consumed in the US

http://www.globalcommissionondrugs.org/wp-content/uploads/2012/03/GCODP-THE-NEGATIVE-IMPACT-OF-DRUG-CONTROL-ON-PUBLIC-HEALTH-EN.pdf

# Outcomes of prescription opioid dose escalation for chronic pain: results of a prospective cohort study, 2020

- N: 517 from Kaiser Permanente and VA, Portland OR
- Dose increase was associated with improvement of pain in 3% of participants

Morasco BJ, Smith N et al. Outcomes of prescription opioid dose escalation for chronic pain: results of a prospective cohort study. Pain, 2020;161(6):1332-1340

# Drug Overdose Masked as Cardiac Deaths

- Published national mortality estimates based on recognized overdoses may be a substantial underestimate of the true burden, because occult overdose deaths masquerading as sudden cardiac deaths are missed without postmortem toxicologic analysis
- 525 autopsied OHCA deaths among persons aged 18 to 90 years from Feb. 1, 2011, to March 1, 2014, in San Francisco and 242 OHCA deaths with autopsies from March 1, 2014, to Dec. 31, 2017.
- 15 percent of the deaths in the initial cohort and 22.3 percent in the extended cohort were adjudicated as occult overdose. Those with overdose deaths were younger than those with nonoverdose OHCA deaths, and were more often White or Black than Asian or Latino

Annals of Internal Medicine, August 11, 2020

# Is tramadol a safer option?

- People receiving tramadol alone after surgery had similar to somewhat higher risks of prolonged opioid use compared with those receiving other short acting opioids.
- Reclassification of tramadol to higher schedule is recommended.

Thiel C, Habermann E, Hooten W. M., et al. Chronic use of tramadol after acute pain episode: cohort study. BMJ 2019;365:l1849

# County Characteristics of Opioid Use

| County (3,100 counties) | Lower opioid use | Higher opioid use |
|---|---|---|
| Voted Republican in 2016 | 38.67% | 59.96% |
| Median household income | $60,577 | $45,269 |
| Disabled | 20,76% | 29.80% |
| Rurality | 1.54 | 2.93 |
| No high school diploma | 84.32% | 87.26% |
| Unemployed | 8.13% | 9.48% |

# Prevalence of Opioid Prescribing/ States

| State | 2012<br>Scripts per 100 people | 2017<br>Scripts per 100 people |
|---|---|---|
| **US total** | 81.3 | 58.7 |
| **Alabama** | 143.8 | 107.2 |
| **California** | 56.4 | 39.5 |
| **New York** | 51.8 | 37,8 |
| **Indiana** | 110.5 | 74.2 |

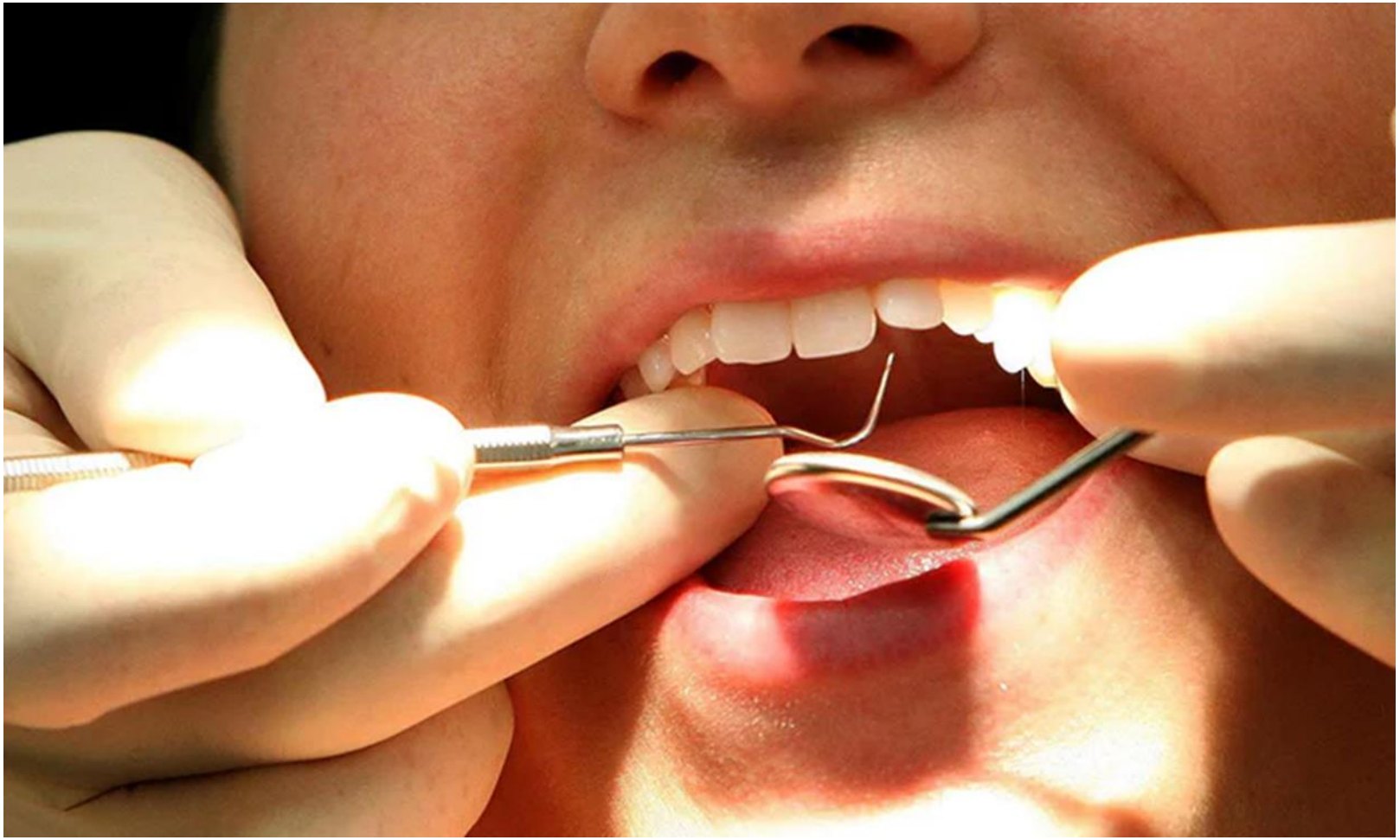
https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

# Prevalence of Opioid Prescribing/ Counties

| State/Neighboring County | 2017<br>Scripts per 100 people |
|---|---|
| CA/ Sierra | 12.4 |
| CA/ Nevada | 70.7 |
| IN/Spenser | 27.2 |
| IN/Floyd | 115.9 |
| IN/Hamilton | 46.9 |
| IN/Howard | 113.4 |

https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

# Dentists



# ER opioid prescribing for dental patients

- Higher proportion of Medicaid beneficiaries (4.9%) had dental-related visits versus commercially insured patients (1.3%),
- For both groups, the highest rate of dental-related emergency department visits was seen for the 18- to 34-year-old age group.
- The most common diagnoses (e.g., caries) were similar between groups.
- Within seven days of a dental-related emergency department visit, prescriptions for an opioid were filled by about 50% of both Medicaid and commercial patients.
- 39.6% of Medicaid patients and 42.0% of commercial patients filled an opioid prescription.

Rebecca M. Roberts, MS, et al. Antibiotic and opioid prescribing for dental-related conditions in emergency departments. J Amer Dent Ass, March 2020;(151)3: 174–181.e1

# Taking Opioids For Wisdom Teeth Removal Nearly Triples Risk Of Additional Use

- People aged 13 to 30 who filled an opioid prescription immediately before or after having the dental procedure were 2.7 times more likely than their peers to fill another opioid prescription over the next year
- Dentists should consider NSAIDs as the first-line therapy for acute pain management

Harbaugh C; Nalliah R, Hu HM, et al Persistent Opioid Use After Wisdom Tooth Extraction. JAMA. 2018;320(5):504-506

# Dental opioid overprescribing

- Cross-sectional analysis of a population-based sample of 542,958 U.S. commercial dental patient visits between 2011 and 2015
- 29 percent of prescribed opioids exceeded the recommended morphine equivalent for appropriate acute pain management.
- Fifty-three percent of prescribed opioids exceeded the recommended three-day supply.
- Those most likely to have opioids prescribed inappropriately were patients aged 18 to 34 years, men, patients residing in the Southern United States, and those receiving oxycodone.
- During the study period, there was an increase noted in the proportion of opioids that exceeded the recommended morphine equivalents, whereas there was no change in opioids exceeding the recommended three-day supply.

Suda K, Zhou J, Rowan S, et al Overprescribing of Opioids to Adults by Dentists in the U.S., 2011–2015 Am Jor Prev Med Feb 3, 2020

# Alternatives to Opioids

Combining ibuprofen and acetaminophen for acute pain management after third-molar extractions: Translating clinical research to dental practice.

Moor P, Hersh E. ADA 2013;(144)8:898-908

# Veterinarians

# 189 Colorado Veterinarians Surveyed

- 13% of surveyed veterinarians were aware that an animal owner had intentionally made an animal ill, injured an animal, or made an animal seem ill or injured to obtain opioid medications
- 44% were aware of opioid abuse or misuse by either a client or a veterinary practice staff member
- 12% were aware of veterinary staff opioid abuse and diversion.

Mason D, Tenney L, Newman S. The Center for Health, Work, & Environment and the Department of Environmental and Occupational Health, Colorado School of Public Health, University of Colorado, September 2018, Vol 108, No. 9

# Neuropathy

# Long-Term Opioids and Polyneuropathy

- Long-term use of opioids did not improve any functional status markers.
- Long-term opioids associated with worse functional status, adverse events in polyneuropathy (1)
- Pain physicians saw one-fourth of patients with polyneuropathy who were on long-term opioid therapy, but they were only the prescribers of opioids to 3.7%
- Neurologists, although often involved with diagnosing and managing polyneuropathy in these patients, were unlikely to be the prescribers of long-term opioids. (2)


1. Hoffman EM, Watson JC, St Sauver J, Staff NP, Klein CJ. Association of long-term opioid therapy with functional status, adverse outcomes, and mortality among patients with polyneuropathy [JAMA Neurol, published online May 22, 2017
2. Levy B, Paulozzi L, Mack KA, Jones CM. Trends in opioid analgesic-prescribing rates by specialty, US, 2007-2012. Am J Prev Med. 2015;49(3):409-413

# Back Pain

# Less than 1/3 of Prescribed Opioids Used

- 10,000 surgical patients
- Prospective data on 539 surgical patients who were discharged after one of 19 general, orthopedic and urologic surgical procedures
- The median opioid use after surgery was 27% of the total prescribed
- Only 18% of patients reported having received instructions on disposing of unused quantities.

Fujii MH, Hodges AC, Russell RL, et al. Post-discharge opioid prescribing and use after common surgical procedure. J Am Coll Surg. 2018;226(6):1004-1012

# Opioids in Knee Osteoarthritis 2020 data

- Data from 9283 participants in 18 randomized clinical studies were included in the study.
- The findings showed that compared with placebo, opioids had only small benefits in terms of pain and function in OA.
- Treatment with opioids of any strength had little benefit on quality of life, but increased risk for harms.
- Strong vs weak/intermediate opioids had lower efficacy and worse safety in the management of OA.

Osani MC, Lohmander LS, Bannuru RR. Is there any role for opioids in the management of knee and hip osteoarthritis? A systematic review and meta-analysis [published online June 25, 2020]. Arthritis Care Res. doi:10.1002/acr.24363

# Opioids for Surgical Procedures Clinical Practice Guidelines (2018)

| Type of Surgery | Number of 5mg ME tablets |
|---|---|
| **Orthopedic Surgery** | |
| Arthroscopic partial meniscectomy: | 0-10 |
| Arthroscopic anterior cruciate ligament (ACL)/posterior cruciate ligament (PCL) repair | 0-20 |
| Arthroscopic rotator cuff repair | 0-20 |
| Open reduction and internal fixation (ORIF) of the ankle | 0-20 |
| **Gynecologic Surgery and Obstetric Delivery** | |
| Open hysterectomy | 0-20 |
| Uncomplicated cesarean delivery | 0-10 |
| Uncomplicated vaginal delivery | 0 |
| Minimally invasive hysterectomy: | 0-10 |

# Opioids for Surgical Procedures Clinical Practice Guidelines (2018)

| Type of Surgery | Number of 5mg ME tablets |
|---|---|
| **General Surgery** | |
| Laparoscopic cholecystectomy | 0-10 |
| Laparoscopic inguinal hernia repair, unilateral | 0-10 |
| Open inguinal hernia repair, unilateral | 0-15 |
| Open umbilical hernia repair | 0-10 |
| **Breast Surgery** | |
| Partial mastectomy without sentinel lymph node biopsy | 0-10 |
| Partial mastectomy with sentinel lymph node biopsy | 0-15 |
| **Thoracic Surgery** | |
| Video-assisted thoracoscopic wedge resection | 0-20 |

# Opioids for Surgical Procedures Clinical Practice Guidelines (2018)

| Type of Surgery | Number of 5mg ME tablets |
|---|---|
| **Urologic Surgery** | |
| Robotic retropubic prostatectomy | 0-10 |
| **Otolaryngology** | |
| Thyroidectomy, partial or total | 0-15 |
| Cochlear implant | 0 |
| **Cardiac Surgery** | |
| Coronary artery bypass grafting | 0-20 |
| Cardiac catheterization | 0 |

Overton HN, Hanna MN, Bruhn WE, Hutfless S, Bicket MC, Makary MA, et al. Opioid-Prescribing Guidelines for Common Surgical Procedures: An Expert Panel Consensus. J Am Coll Surg. 2018 Oct. 227 (4):411-418.

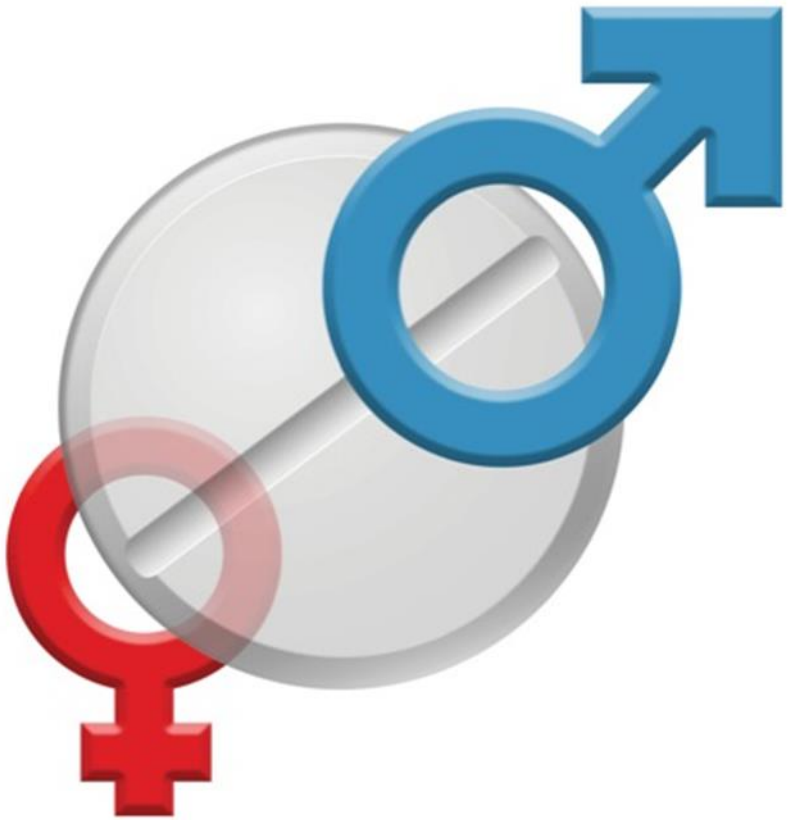
# Headache

# Opioids and Headache

- High frequent headache recurrence, typical side effects of opioids, increased risk of chronification, and development of addiction in primary headache patients treated with opioids. On the basis of the current scientific data, opioids should be avoided in acute and prophylactic treatment of primary headache disorders (1)
- Tolerance, dependence, and addiction are prominent issues. (2)
- PCP - Just 34% were aware that opioids can cause medication-overuse headache. (3)


- Totzeck A1, Gaul C. The role of opioids in the treatment of primary headache disorders Schmerz. 2014 Apr;28(2):135-40.
- Levin M, Opioids in headache. Headache. 2014 Jan;54(1):12-21.
- Minen MT1, Loder E2, Tishler L3, Silbersweig D3. Cephalalgia. Migraine diagnosis and treatment: A knowledge and needs assessment among primary care providers. 2016 Apr;36(4):358-70.

# Opioid prescribing  Women vs. Men

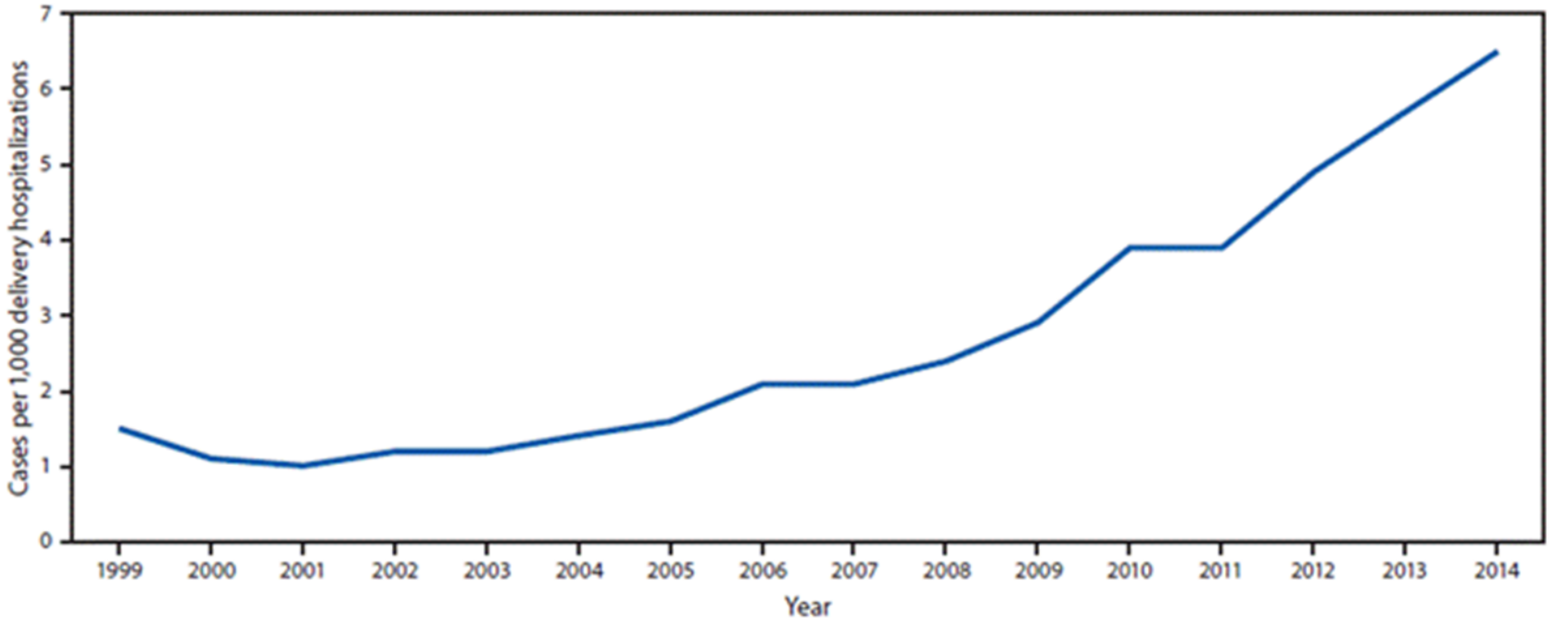


# Opioid prescribing  Women vs. Men

- Women also have a greater risk for death while receiving treatment for abuse
- Between 1999 and 2016, deaths from overdose increased by 404% in men and 583% in women
- This difference is said to be attributable to multiple factors, including the lower percentage of emergency medical services administering naloxone to women than men, and more rapid development of drug use disorders in female patients

Mazure C, Fiellin D. The Lancet 2018;392[10141]:9-11.

# Opioid use disorder per 1,000 delivery – 28 States




1. National Inpatient Sample (NIS),† Healthcare Cost and Utilization Project (HCUP), United States, 1999–2014

2. Haight SC, Ko JY, Tong VT, Bohm MK, Callaghan WM. Opioid Use Disorder Documented at Delivery Hospitalization — United States, 1999–2014. MMWR Morb Mortal Wkly Rep 2018;67:845–849

# Opioid Use Prior to Discharge After Cesarean Section Tied to Later Use

Women who take less opioid pain medication in the 24-hour period before being discharged from the hospital after a cesarean delivery also use less opioid medication during the four weeks following discharge

Carrico JA, Mahoney K. Predicting Opioid Use Following Discharge After Cesarean Delivery. Ann Fam Med. 2020 Mar;18(2):118-126. doi: 10.1370/afm.2493.

# Opioid Prescribing After Childbirth and Risk for Serious Opioid-Related Events: A Cohort Study, 2020

- Women aged 15 to 44 years enrolled in Tennessee Medicaid.
- 209,215 births to 161,318 women, 59 percent of vaginal births and 91 percent of cesarean births involved filling an opioid
- 10.5 and 24.4 percent, respectively, involved filling a second opioid prescription
- Risk increasing with the number of prescriptions filled
- Adjusted hazard ratios for one, two, and three or more prescriptions compared with no prescription: 1.4, 3.6, and 7.0, respectively

Osmundson S, et al. Opioid Prescribing After Childbirth and Risk for Serious Opioid-Related Events: A Cohort Study, Ann Intern Med. 2020 Jun 9

# Increase in Infection Diseases and Foster Care

- Opioid use linked to increase in HIV and Hep. C - 167% from 2010 to 2017 (1)
- Children in Foster Care increased by 7% (40,000) between 2012 and 2016 attributed to parents' opioid related overdoses lead in foster care. The States with highest overdose rates lead in foster care increase (2)


- The President's Comission on Combatting Drug addiction and the Opioid Crisis, Final Report http://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf
- Children's Bureau, Office of Administration for Children' & Families. Adoption and foster care statistics http://acf.hhs.gov/cb/research-data-technology/statistics-research/afcars

# Mental Illness

# Opioids and Mental Illness

- 16% patients with mental illness use 51% of opioids
- More depression symptoms were associated with opioid use (11.31% vs 8.65%)

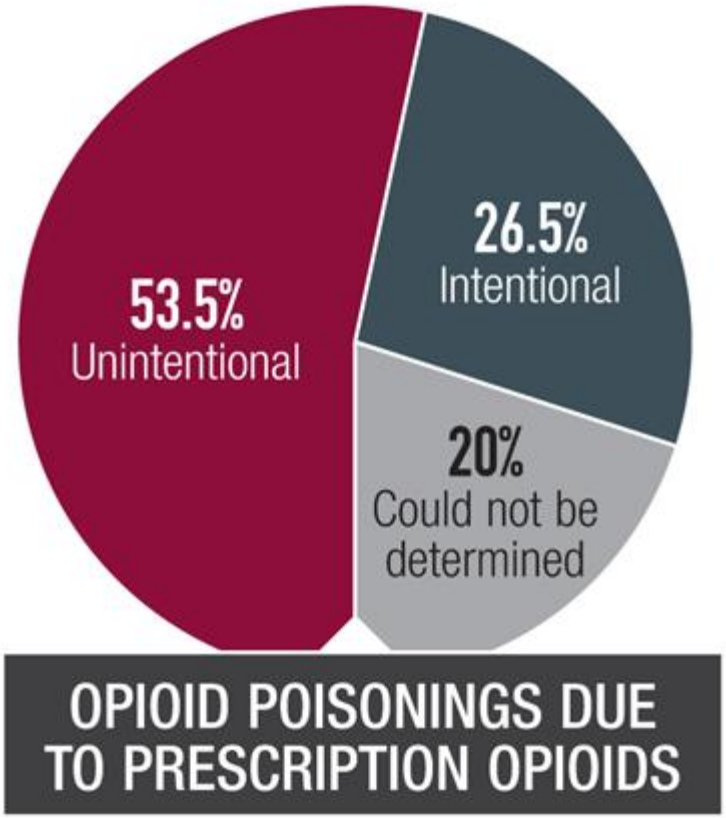

- J Am Board Fam Med 2017; 30:407– 417
- Chuang E, Gil EN, Gao Q, Kligler B, McKee MD. Relationship between opioid analgesic prescription and unemployment in patients seeking acupuncture for chronic pain in urban primary care [published online September 3, 2018]. Pain Med

# Back Pain and Depression

- The analysis of nationwide data from 2004 to 2009 found that patients with back pain who screened positive for depression were more than twice as likely to be prescribed an opioid.
- Over a year's time, they also got more than twice the typical dose.

Smith JA, Fuino RL, Pesis-Katz I, et al. Differences in opioid prescribing in low back pain patients with and without depression: a cross-sectional study of a national sample from the United States. Pain Reports. 2017

# Opioid Overdose




King S. Opioids, suicide, mental disorders and pain. Psych Times 2018;(35)11

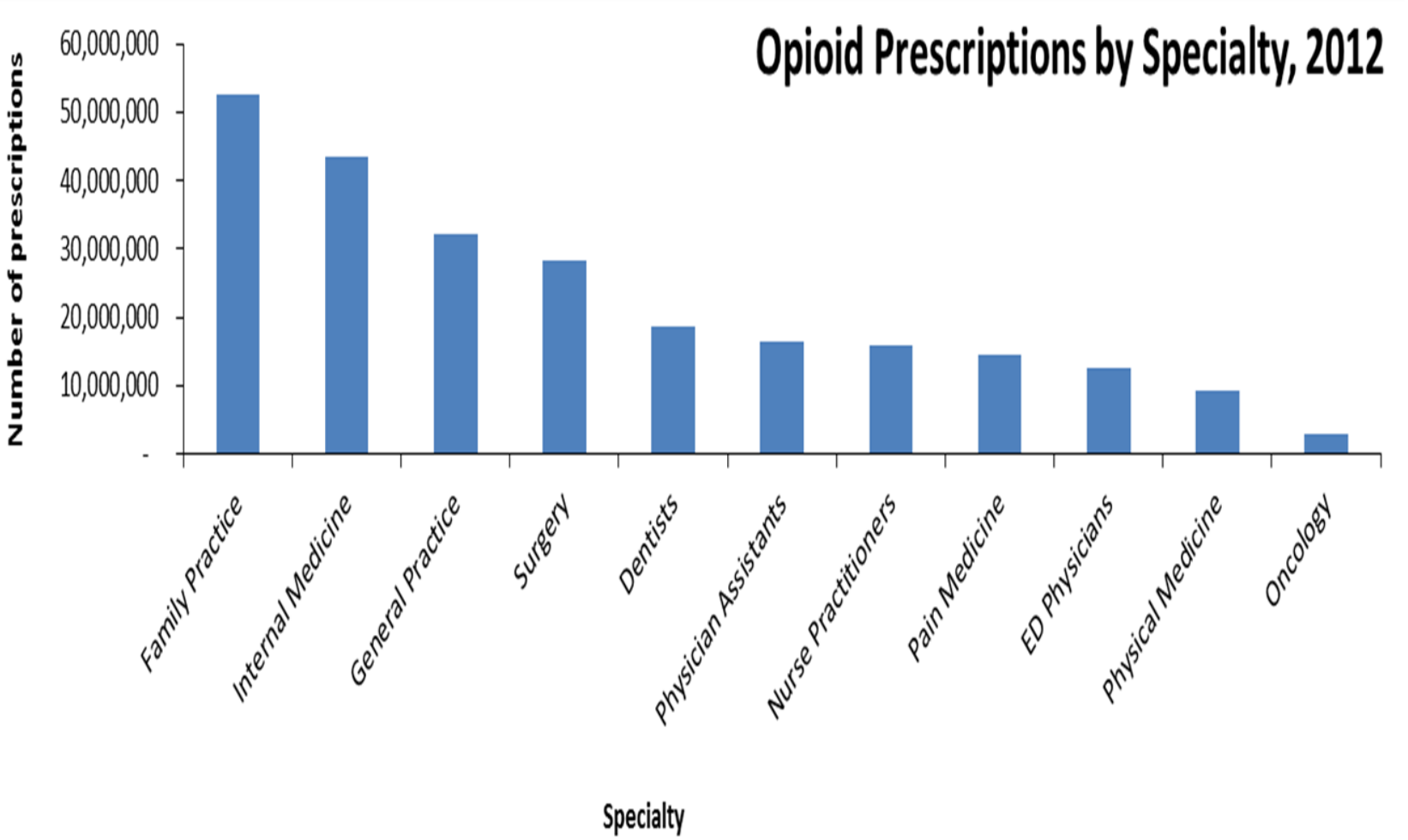
# Who Prescribes (too much) Opioids?

# Opioid prescribing. Latest data - 2017

- In 2017, the top 1% of prescribers accounted for more than a quarter of all opioid prescriptions
- among the bottom 99% of prescribers, greater compliance with Centers for Disease Control and Prevention opioid prescribing guidelines was observed
- The top 1% of clinicians prescribed 1000-fold that of the median centile
- Investigators recommended that intervention efforts to reduce opioid overprescribing target the highest-dispensing subgroup of clinicians
- Among the top centile of opioid prescribers, the most common specialties were family medicine (24%), physical or pain medicine and rehabilitation (14%), anesthesiology (14%), and internal medicine (13%)

Kiang MV, Humphreys K, Cullen MR, Basu S. Opioid prescribing patterns among medical providers in the United States, 2003-17: retrospective, observational study. BMJ. 2020;368:l6968

# Opioid Prescribing by Specialty




IMS Health, National Prescription Audit, United States, 2012

# Opioid Use

65% of abused prescription opioids are accessed through a friend or family member who received that prescription from a physician.

US Department of Health and Human Services. SAMHSA. Results from the 2014 national survey on drug use and health: detailed tables. Available at: https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.pdf.

# Trend down started in 2016

Pain treatments were the second largest therapy area, with 460 million prescriptions, 503 million when adjusted for the smaller proportion of long-duration pain prescriptions, (Hypertension represents the largest therapy area by dispensed prescriptions, with 721 million prescriptions) and declined 1% from 2015 as much of the country continues to implement dispensing volume controls on narcotic pain medicines.

# Who is Responsible?

- Pharmaceutical companies
- Healthcare providers
- Distributors
- Medical societies
- Government
- Patients
- Insurance companies

# Insurers' Policies Fuel the Opioid Epidemic

2017 coverage policies of 15 Medicaid plans, 15 Medicare Advantage plans and 20 commercial insurers analyzed:

- Quantity limits
- Step therapy
- Prior authorization
- Exclusion of buprenorphine

Lin D, Jones C, Compton W, et al. Prescription Drug Coverage for Treatment of Low Back Pain Among US Medicaid, Medicare Advantage, and Commercial Insurers JAMA Network Open. 2018;1(2):e180235

# Humana.

Humana Clinical Pharmacy Review
P.O. Box 33008
Louisville, Ky. 40232-3008
1-800-555-2546

**Attention:** **Response needed by 08/12/2018 07:12:36 EST**

**Prescriber name: Amanda Shrum**

**Fax sent to 317-805-5501**

**Sender fax number: 1-844-211-3075**

**Member name:** [redacted]

**Member DOB:** [redacted]

**EOC ID number:** [redacted]

**Drug requested: BUPRENORPHINE 5 MCG/HR PATCH**

We received your recent request for prescription coverage authorization for the member and drug referenced above. To finalize the authorization, we need additional information from you that was not included with the original request.

***Please answer the following questions:***

Q1. Please explain why Humana's formulary alternative would be CLINICALLY ineffective or inappropriate for the patient. Formulary alternative(s) is/are: fentanyl transdermal patch, Xtampza ER capsule sprinkle, Embeda capsule extend release oral only, and tramadol ER tablet extended release 24 hr

Please fax **1-844-211-3075** or call **1-844-750-1055** to provide the necessary information. This phone line is open Monday through Friday, 8 a.m. to 8 p.m. EST.

If this information is not received by **08/12/2018 07:12:36** Humana will have to make a determination based only on the information available, which may result in a denial. In the case of a denial, you will need to request reconsideration through Humana's Grievance and Appeals department. However, if you wish to still submit this information after the before-mentioned time we will transfer it to Grievance and Appeals for you.

Please understand that the appeal process will take longer than the initial review.

Thank you for your continued care of our members.

# Health Plans

03/15/2018

Dr. DMITRY ARBUCK
VIA FACSIMILE: (317) 805-1501

RE: [redacted]

Dear Dr. DMITRY ARBUCK:

On 03/15/2018 IU Health Plans (the "Plan") reviewed the Prior Authorization Request submitted for BUTRANS Patch Weekly APPLY ONE PATCH EVERY WEEK. After review of the available clinical information, the request for BUTRANS Patch Weekly APPLY ONE PATCH EVERY WEEK is denied because:

The information provided does not show that the member has tried and failed: [1] 2 generic prescription-strength non-steroidal anti-inflammatory drugs (NSAIDs) for at least 1 month each, and [2] two of the following for at least 1 month each: hydrocodone/acetaminophen, morphine sulfate, oxycodone, oxycodone/acetaminophen, or tramadol. Please note that chart note documentation of these medication trials is needed. This decision is based on criteria for BUTRANS 10.0MCG/HR Patch Weekly found in policy RX.PA.442 Butrans approved by the health plan pharmacy and therapeutics committee.

This denial is a determination of coverage for the requested medication based on the Plan's medical necessity guidelines and benefit policies. It is not a substitute for the independent judgment of the treating physician concerning the appropriate course of treatment. If the member proceeds with the denied requested medication, then he or she will be held financially responsible based on the Plan's denial of this request. Should you or the member wish to receive a copy of the Plan's clinical criteria, or benefit provision on which this decision has been based, copies will be sent at no cost upon request. You may request a discussion with the individual that made the adverse determination by calling the Pharmacy Services Department at 855.859.1719.

If the Member's case is urgent:

- You may request an expedited appeal, with the Member's consent. A Member's physician must certify that the denial involves a medical condition that poses a significant and immediate threat to the Member's health. You may also request an expedited external review at the same time, with the Member's consent. Request an expedited appeal or expedited external review by calling Pharmacy Services at 866.822.6504.

Anthem UM Services, Inc.
Grievances and Appeals
P.O. Box 105568
Atlanta GA 30348-5568

**Anthem UM Services, Inc.**

October 25, 2018

Indiana Polyclinic
Attn: Dmitry Arbuck, MD
201 Pennsylvania Parkway, Ste. 200
Indianapolis, IN 46280-1393

Case number: 0513232494
Member name: [redacted]
ID number: [redacted]

Dear Provider:

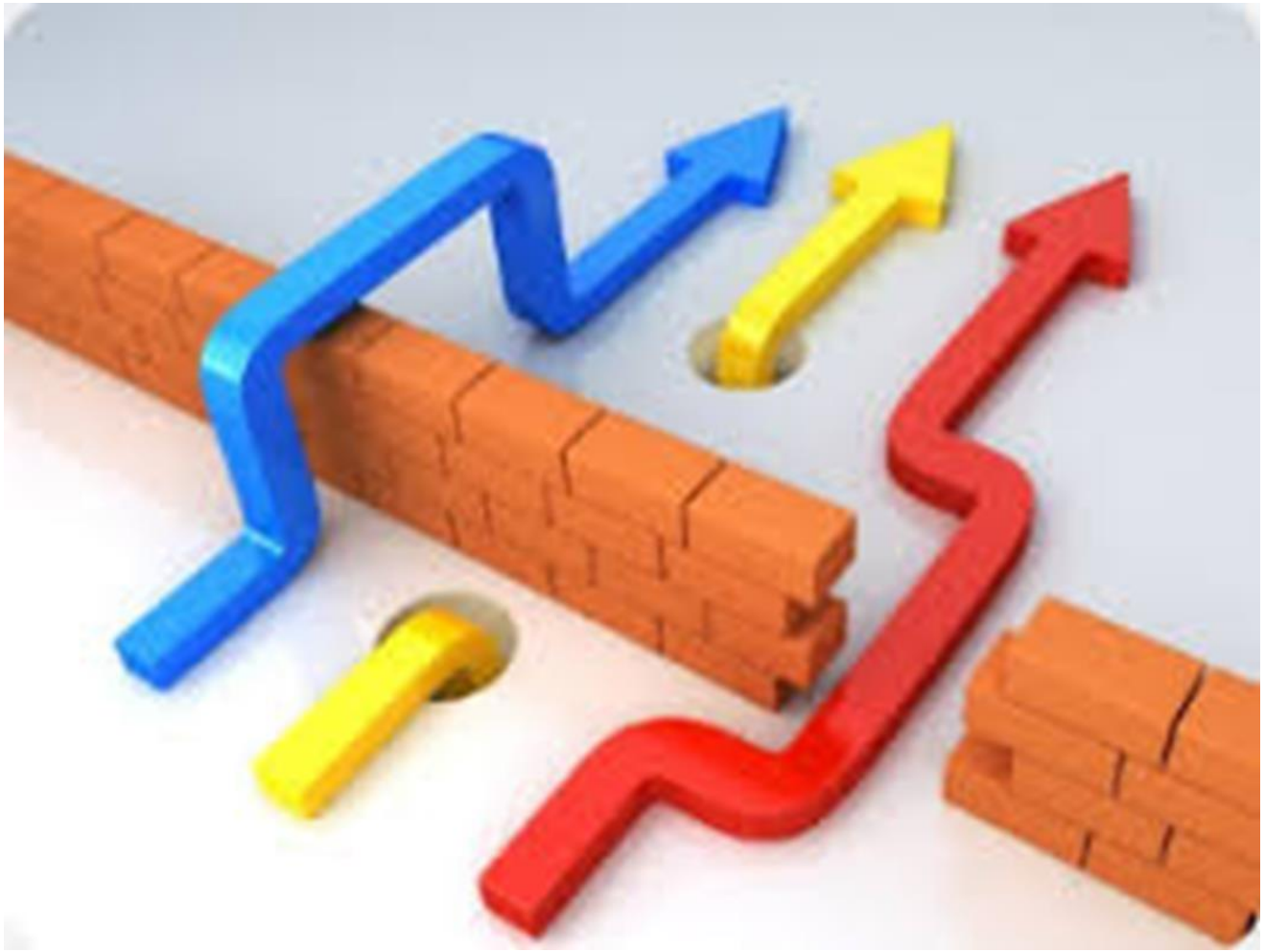
On October 22, 2018, we received your request for an external review of our decision not to make an exception to cover a non-formulary drug (Belsomra 20mg tablet). A drug is non-formulary when it isn't on your health plan's formulary list. We sent the request to an Independent Review Organization (IRO) on October 25, 2018. Based on the IRO's review, coverage remains denied.

The patient has chronic insomnia. You have ordered a (belsomra). The patient's Plan requires that all covered formulary drugs would be tried and failed first. The patient's Plan requires the Plan's preferred drug would not be as effective as the requested non-formulary drug (belsomra). The Plan also requires would have more adverse effects than the requested non-formulary drug (belsomra). After reviewing the information provided by you, we have determined the patient does not meet criteria for an approval of Belsomra. The patient has not yet tried similar drugs such as estazolam, phenobarbital, and ramelteon. There is no evidence that the requested drug (belsomra) is better than other similar drugs (i.e. i.e.estazolam, phenobarbital, ramelteon) to treat the patient's condition. As such, this is not a covered benefit. This was based on the patient's Plan.

This decision is binding (final).

If you have any questions about this letter, please call Member Services at the phone number on your ID card.

# Alternatives



# 5-Point Strategy To Combat the Opioid Crisis (Department of Health and Human Services)

1. Access: Better Prevention, Treatment, and Recovery Services
2. Data: Better Data on the Epidemic
3. Pain: Better Pain Management
4. Overdoses: Better Targeting of Overdose-Reversing Drugs
5. Research: Better Research on Pain and Addiction

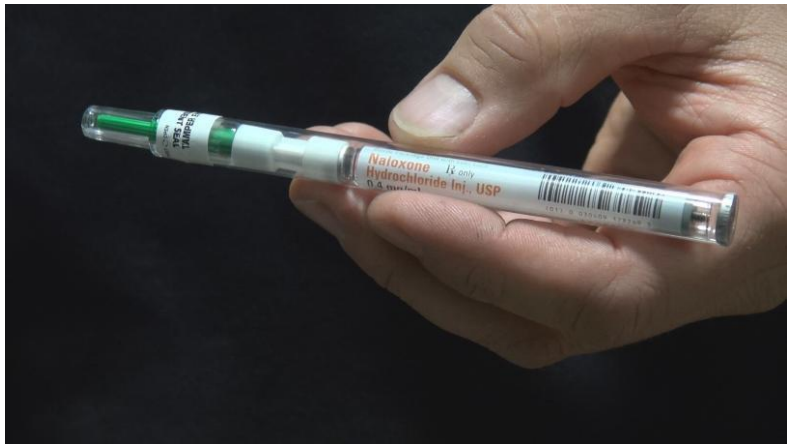
# Important Steps

Managing laboratory screening, educating patients about their medications, and encouraging naloxone use and opioid tapering

Giannitrapani KF, Glassman PA, Vang D, et al. Expanding the role of clinical pharmacists on interdisciplinary primary care teams for chronic pain and opioid management. BMC Fam Pract. 2018;19(1):107.


NDC 69547-353-02
0.1 mL intranasal spray per unit
For use in the nose only
Rx Only
NARCAN® (naloxone HCl)
NASAL SPRAY 4 mg
DO NOT TEST DEVICES OR OPEN BOX BEFORE USE.
Use for known or suspected opioid overdose in adults and children.
This box contains two (2) 4-mg doses of naloxone HCl in 0.1 mL of nasal spray.
Two Pack
CHECK PRODUCT EXPIRATION DATE BEFORE USE.
OPEN HERE FOR QUICK START GUIDE
4 mg
NARCAN® NASAL SPRAY


Evzio
naloxone HCl injection, USP
0.4mg auto-injector
NDC
60842-030-01
Rx Only
PULL
DEVICE UP
FROM THIS CASE
FRONT
Evzio
naloxone HCl injection, USP
0.4mg auto-injector
USE FOR OPIOID EMERGENCIES
SUCH AS SUSPECTED OVERDOSE
Seek Emergency Medical Attention
Instructions for use found inside on device
Includes Voice Instructions from a Speaker


Naloxone
Hydrochloride Inj. USP

# Benzodiazepines

- 5 year death rates among 21,492 patients with schizophrenia
- Any antipsychotic or antidepressant exposure compared with no medication exposure lowered mortality in patients by 15% to 40%
- Benzodiazepine exposure increased mortality by 70%
- Among first-episode patients with high benzodiazepine exposure, mortality hazard ratio (HR) was 3.86
- Moderate benzodiazepine exposure was associated with higher cardiovascular and suicide mortality (HRs, 1.14 and 1.49), as was high benzodiazepine exposure (HRs, 1.98 and 2.16).

Tiihonon J et al. Mortality and cumulative exposure to antipsychotics, antidepressants, and benzodiazepines in patients with schizophrenia: An observational follow-up study. Am J Psychiatry 2015 Dec 7

# Smoking: Predictor of Aberrant Drug Use

- SOAPP includes tobacco use as a factor in determining risk (1,2)
- Tobacco use is highly prevalent among substance misusers (3)
- Smoking increased desire to abuse drugs in an addict population (N = 160) (3)
- Smoking may be used as a form of substance replacement in those trying to abstain (3,4)


1.Coambs et al. Pain Res Manage. 1996;1:155.

2. Butler et al. Pain. 2004;112:65.

3. Rohsenow et al. Addict Behav. 2005;30:629.

4. Conner et al. Exp Clin Psychopharmacol. 1999;7:64

# Misuse Risks

- Younger
- Male
- Past substance abuse
- Previous drug or DUI conviction
- No relationship between pain scores and misuse

# A Chronic Pain Patient and an Addicted Patient

## Pain patient

- Not out of control with medications
- Medications improve quality of life
- Will want to decrease medication if side effects are present

## Addicted patient

- Out of control with medications
- Medications cause decreased quality of life
- Medication continues or increases despite side effects

Schnoll SH, Finch J. J Law Med Ethics.1994;22(3):252-256.

# A Chronic Pain Patient and an Addicted Patient

## Pain patient

- Concern about the physical problem
- Follows the agreement for the use of the opioids
- Frequently has medicines leftover

- Schnoll SH, Finch J. J Law Med Ethics.1994;22(3):252-256.

## Addicted patient

- Unaware or in denial about any problems
- Does not follow the agreement for use of the opioids
- Does not have medicines leftover, loses prescriptions, and always has a “story”

# The Indiana Prescription Monitoring Program (PDMP)

- Check INSPECT (Indiana Scheduled Prescription Electronic Collection & Tracking Program)
- Doctor Shopping
- Rx History Reports
- Person of Interest Notifications
- Practitioner Self-Lookup

http://www.in.gov/pla/inspect/files/Law_Enforcement_INSPECT_Packet.pdf

# Indiana Senate Enrolled Act #221

- January 1, 2019 - all prescribers who hold CSR credentials are required by Indiana law to register with INSPECT and access INSPECT to search for and review patient reports prior to prescribing a benzodiazepine or opioid.
- Failure to register is a Class A misdemeanor.

# Positive Trend

- Between 2013 and 2017 the number of opioid prescriptions decreased by more than 55 million
- 22.2% decrease in opioid prescribing nationally
- In 2017 medical professionals accessed PDMPs 300 million times – 121% increase from 2016
- In 2017 550,000 medical professionals took opioid related training

AMA Press Release, May 31, 2018 www.ama-assn.org/ama-report-shows-national-progress-toward-reversing-opioid-epidemic.

# Life Expectancy Up, Opioid-Related Deaths Down

- Life expectancy for Americans rose by one month in 2018 to 78.7 years compared with 2017
- Drug overdoses—largely from opioids—went down from 70,237 in 2017 to 67,367 in 2018, for a decline of 4.1%

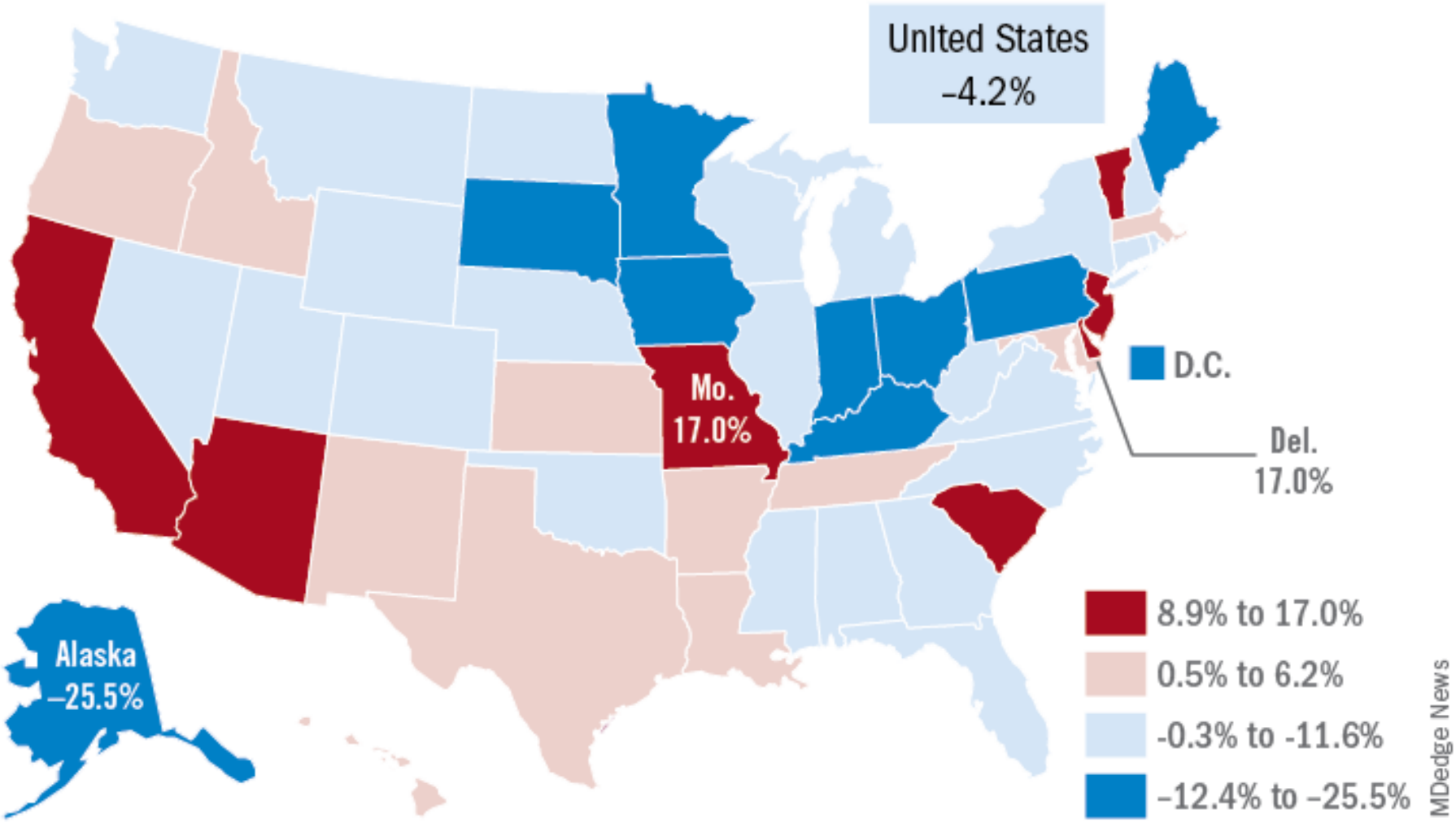
Xu J, Murphy SL, et al. Mortality in the United States, 2018, NCHS Data Brief, (355), January 2020

# More progress, 2020

- Continued increase in Prescription Drug Monitoring Program registrations (a 64.4 percent increase from 2018 and a more than 1,100 percent increase since 2014).
- More physicians are certified to treat opioid use disorder. More than 85,000 physicians and a growing number of nurse practitioners and physician assistants are certified to treat opioid use disorder with in-office buprenorphine (an increase of more than 50,000 since 2017).
- There were more than 1 million naloxone prescriptions dispensed in 2019 (twice as many as in 2018 and a 649 percent increase from 2017).

Opioid Task Force 2020 Progress Report , American Medical Association (AMA).

# Change in reported drug-overdose deaths, 2017 to 2018




**Note:** Based on data from the National Vital Statistics System.

**Source:** National Center for Health Statistics

# Questions?